

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

MARY JO HERRNANDEZ and LUIS A.
HERRNANDEZ,

Plaintiffs,

V.

STRYKER CORPORATION, a foreign
corporation, *et al.*,

Defendants.

CASE NO. C14-0613RSM

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

I. INTRODUCTION

This matter comes before the Court on Defendants’ Motion to Dismiss Plaintiff’s First Amended Complaint under Federal Rules of Civil Procedure 12(b)(6). Dkt. #14. Defendants argue that Plaintiffs’ claims are explicitly preempted from suit by the United States Supreme Court’s decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S. Ct. 999 (2008). *Id.* Defendants further argue that Plaintiffs’ claims independently fail under an implied preemption analysis. *Id.* Finally, Defendants argue that Plaintiffs have failed to adequately plead sufficient facts to meet the appropriate notice pleading standard. *Id.* Plaintiffs argue that their claims may proceed because they are “parallel claims,” and therefore allowed under *Riegel*, and that they have pled sufficient facts to meet the applicable pleading standard. Dkt. #16. For the

1 reasons set forth below, this Court disagrees with Plaintiffs and GRANTS Defendants' motion
2 to dismiss.

3 II. BACKGROUND

4 This matter involves product liability allegations related to a hip replacement. On
5 March 28, 2005, Plaintiff Mary Jo Hernandez underwent a primary right total hip replacement,
6 receiving the Stryker Trident™ acetabulum and Secur-Fit stem with a ceramic-on-ceramic
7 bearing surface. Dkt. #10 at ¶ 3.6. After the surgery, she experienced increasing pain, which
8 ultimately became disabling in December of 2011. *Id.* at ¶ ¶ 3.7-3.9. As a result, the hip
9 system was removed on February 27, 2012. *Id.* at ¶ 3.10. Plaintiff's orthopedic surgeon
10 determined that the device had failed. *Id.*

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13 On March 21, 2014, Plaintiffs filed suit in King County Superior Court. Dkt. #4. Ms.
14 Hernandez seeks compensation for her injuries allegedly sustained as a result of the
15 implantation, and later removal, of the Trident system. *See* Dkts. #4 and #10 at ¶ 3.5. Mr.
16 Hernandez brings a derivative loss of consortium claim. *Id.* Plaintiffs allege six state law
17 causes of action, including: 1) strict liability in tort; 2) negligence; 3) breach of express and
18 implied warranties; 4) failure to warn; 5) products liability; and 6) failure to monitor. Dkt. #10
19 at ¶ ¶ 4.1-4.52. Defendants have removed the case to this Court on the basis of diversity
20 jurisdiction, and now move to dismiss the case in its entirety. Dkt. #1.

21 III. DISCUSSION

22 A. Standard of Review Under 12(b)(6)

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24 On a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure
25 12(b)(6), all allegations of material fact must be accepted as true and construed in the light
26 most favorable to the nonmoving party. *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337-38
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1 (9th Cir. 1996). However, the court is not required to accept as true a “legal conclusion
2 couched as a factual allegation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl.*
3 *Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The Complaint “must contain sufficient factual
4 matter, accepted as true, to state a claim to relief that is plausible on its face.” *Id.* at 678. This
5 requirement is met when the plaintiff “pleads factual content that allows the court to draw the
6 reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* Absent facial
7 plausibility, Plaintiffs’ claims must be dismissed. *Twombly*, 550 U.S. at 570.

9 The Court generally may not consider material beyond the pleadings in ruling on a
10 motion to dismiss. *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). However,
11 where documents are referenced extensively in the Complaint, form the basis of Plaintiff’s
12 claim, or are subject to judicial notice, the Court may consider those documents in the context
13 of a motion to dismiss. *United States v. Ritchie*, 342 F.3d 903, 908-09 (9th Cir. 2003).
14 Defendants have sought judicial notice of a number of documents outside of the First Amended
15 Complaint, to which Plaintiffs have not objected. *See* Dkts. #15 and #16. Accordingly, the
16 Court has taken judicial notice of and considers herein the following documents: 1) Trident™
17 System PMA Approval Order and Letters, Summary of Safety and Effectiveness Data, and
18 Labeling (Dkt. #15, Exs. 1 and 2); and 2) two FDA Warning Letters (Dkt. #15, Exs. 3 and 4
19 at 6-8).

22 **B. Applicable Regulatory Framework**

23 While the Food, Drug and Cosmetic Act (“FDCA”) has long required approval by the
24 U.S. Food and Drug Administration (“FDA”) of new drugs prior to their introduction into the
25 market, oversight of the introduction of new medical devices was historically left largely to the
26 states. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008).
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1 However, the development of medical devices using new technology – such as “kidney dialysis
2 units, artificial heart valves, and heart pacemakers” – prompted concern among policymakers
3 and the public “about the increasingly severe injuries that resulted from the failure of such
4 devices.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-76, 116 S. Ct. 2240, 135 L. Ed. 2d 700
5 (1996). In response, Congress enacted the Medical Device Amendments (“MDA”) to the
6 FDCA, 21 U.S.C. § 360c, *et seq.*, “which swept back some state obligations and imposed a
7 regime of detailed federal oversight.” *Riegel*, 552 U.S. at 316.
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9 The MDA classifies medical devices into three categories based upon the “risks they
10 present.” *Id.* Medical devices in Class III receive the greatest federal oversight. *Id.* at 317.
11 “In general, a device is assigned to Class III if it cannot be established that a less stringent
12 classification would provide reasonable assurance of safety and effectiveness, and the device is
13 ‘purported or represented to be for a use in supporting or sustaining human life or for a use
14 which is of substantial importance in preventing impairment of human health,’ or ‘presents a
15 potential unreasonable risk of illness or injury.’” *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).
16 New Class III devices must undergo a rigorous premarket approval (“PMA”) process. *Riegel*,
17 552 U.S. at 317. Only a small percentage of new Class III devices (roughly 1% in 2005) are
18 approved annually by the FDA through the PMA process. *Id.*
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21 Once the FDA has approved a medical device for sale under the PMA process, the
22 MDA prohibits the manufacturer from making “changes in design specifications,
23 manufacturing processes, labeling, or any other attribute, that would affect safety or
24 effectiveness” without filing a supplementary premarket approval application and obtaining
25 permission from the FDA to make such changes. *Id.* at 319 (citing 21 U.S.C. §
26 360e(d)(6)(A)(i)); 21 C.F.R. § 814.39(a). Furthermore, following approval, the manufacturer
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1 must report to the FDA any adverse results it has become aware of in patients using the medical
2 device. *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360i). “The FDA has the power to
3 withdraw premarket approval based on newly reported data or existing information and must
4 withdraw approval if it determines that a device is unsafe or ineffective under the conditions in
5 its labeling.” *Id.* at 319-20 (citing 21 U.S.C. §§ 360e(e)(1); 360h(e)).

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7 Medical device manufacturers in general must comply with the FDA’s current good
8 manufacturing practice requirements (“CGMPs”), which set forth a “quality system regulation”
9 and “govern the methods used in, and the facilities and controls used for, the design,
10 manufacture, packaging, labeling, storage, installation, and servicing of all finished devices
11 intended for human use.” 21 C.F.R. § 820.1(a)(1). The CGMPs serve “to ensure that finished
12 devices will be safe and effective and otherwise in compliance with the [FDCA].” *Id.* “They
13 do not specifically address the design, production and marketing requirements for each and
14 every type of medical device. The CGMP requirements, therefore, leave it up to the
15 manufacturer to institute a quality control system specific to the medical device it produces to
16 ensure that such device is safe and effective.” *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271,
17 278-79 (E.D.N.Y. 2009) (citation omitted).

20 **C. History of the Trident™ System**

21 *1. FDA Approval*

22 The FDA approved the Trident™ System for commercial distribution in the United
23 States in February 2003. Dkt. #15, Ex.1 at 7-13. The Trident™ System received FDA
24 approval pursuant to the PMA process and is classified as a Class III medical device. Dkts. #14
25 at 4 and #15, Ex. 1.¹

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28 ¹ Interestingly, in their First Amended Complaint, Plaintiffs do not make any factual
allegations with respect to the Trident™ System’s device classification or that it went through

2. *FDA Warning Letters*

On March 15, 2007, the FDA issued a warning letter to Defendants regarding their Cork, Ireland manufacturing facility. Dkt. #15, Ex. 3. The letter informed Defendants that, after inspecting the facility, the FDA had concluded that certain knee replacement components, hip systems, and a reconstruction and cable system were “adulterated” as defined in 21 U.S.C. § 351(h), “in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, **Code of Federal Relations** (C.F.R.), Part 820.” *Id.* (bold font in original). On November 28, 2007, the FDA issued a warning letter to Defendants regarding their Mahwah, New Jersey facility. The letter informed Defendants that, after inspecting the facility, the FDA had determined that certain hip replacement components and systems, *inter alia*, were “adulterated” as defined in 21 U.S.C. § 351(h), “in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, **Code of Federal Relations** (C.F.R.), Part 820.” *Id.*, Ex. 4 (bold font in original).

3. *Recall*

Defendants voluntarily initiated a recall in 2008.² Dkt. #10 at ¶ 3.23. In June 2008, Defendants recalled the “Trident Hemispherical Acetabular Cluster Shells,” which allegedly was a component in Mrs. Hernandez’s hip system. *See Simoneau v. Stryker Corp.*, 2014 U.S. Dist. LEXIS 43137, *8-9 (D. Conn. Mar. 31, 2014) and Dkt. #10 at ¶ 4.3. While Ms. the PMA process. *See* Dkt. #10. However, they concede as much in their Response to the instant motion. *See* Dkt. #16 at 5.

² Significantly, Plaintiffs do not identify what device or component was recalled in 2008 or how that relates to Ms. Hernandez.

Hernandez alleges that the Trident Hemispherical Acetabular Cluster Shell was a component in the system implanted into her in 2005, she makes no specific allegations with respect to the recall of that component. *See* Dkt. #10 at ¶¶ 3.23 and 4.3.

D. Plaintiffs' First Amended Complaint

Defendants initially argue that the MDA preempts all claims against them in the First Complaint. Having reviewed the Complaint, the parties' submissions, and the expansive case law in this area, the Court finds that Plaintiffs' claims are preempted for the reasons discussed herein.

1. Scope of Federal Preemption Under the MDA

The MDA includes an express preemption provision:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel*, the Supreme Court held that the “requirement[s]” covered by section 360k(a) include common law products liability claims. 552 U.S. at 323-25 (“State tort law . . . disrupts the federal scheme no less than state regulatory law to the same effect.”). The *Riegel* Court noted, however, that section 360k does not prohibit states “from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” *Id.* at 330 (quoting *Lohr*, 518 U.S. at 495). While the MDA does not create a private right of action for a violation of the federal requirements applicable to a medical device, neither does it preempt state tort claims that do not differ from

1 or add to such requirements. *Riegel*, 552 U.S. at 330; *Buckman Co. v. Plaintiffs' Legal Comm.*,
2 531 U.S. 341, 349, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001).

3 In the instant case, Plaintiffs do not dispute that their claims, if they were based on
4 different or additional requirements to those imposed by FDA regulations, would be preempted.
5 Dkt. #16 at 5. They argue, however, that they bring “parallel” claims in this action, which are
6 not precluded. *Id.*

8 2. Plaintiffs' Claims

9 Since the United States Supreme Court's decision in *Riegel*, *supra*, numerous courts
10 across this country have examined the questions facing this Court with respect to the Trident™
11 System. *See, e.g., Simoneau v. Stryker*, 2014 WL 1289426 (D. Conn. March 31, 2014); *Gray v.*
12 *Stryker*, 2013 WL 633120 (S.D. Ind. Feb. 20, 2013); *Bass v. Stryker Corp.*, 669 F.3d 501 (5th
13 Cir. 2012); *Gross v. Stryker Corp.*, 858 F.Supp.2d 466 (W.D. Pa. 2012); *Rhynes v. Stryker*
14 *Corp.*, 2011 U.S. Dist. LEXIS 124510 (N.D. Cal. Oct. 27, 2011); *Desabio v. Howmedica*
15 *Osteonics Corp.*, 817 F.Supp.2d 197 (W.D.N.Y. 2011); *Wilhite v. Howmedica Osteonics Corp.*,
16 833 F.Supp.2d 753 (N.D. Ohio 2011); *White v. Stryker*, 818 F.Supp.2d 1032 (W.D. Ky. 2011);
17 *Funk v. Stryker*, 631 F.3d 777 (5th Cir. 2011), affirming *Funk v. Stryker*, 673 F.Supp.2d 522
18 (S.D. Tex. 2009); *Bausch v. Stryker* 630 F.3d 546 (7th Cir. 2010); *Warren v. Howmedica* 2010
19 WL 5093097 (E.D. Mo. Dec. 8, 2010); *Cornwell v. Stryker Corp.*, 2010 U.S. Dist. 116824 (D.
20 Idaho, Nov. 1, 2010); *Phillips v. Stryker*, 2010 WL 2270683 (E.D. Tenn. June 3, 2010); *Lewkut*
21 *v. Stryker Corp.*, 724 F.Supp.2d 648 (S.D. Tex. 2010); *Anthony v. Stryker Corp.*, 2010 WL
22 1387790 (N.D. Ohio March 31, 2010); *Yost v. Stryker*, 2010 WL 1141586 (M.D. Fla. March
23 23, 2010); *Lemelle v. Stryker Orthopaedics*, 698 F.Supp.2d 668 (W.D. La. 2010); *Horowitz v.*
24 *Stryker Corp.*, 613 F.Supp.2d 271 (E.D.N.Y. 2009); *Hofts v. Howmedica Osteonics Corp.*, 597
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1 F.Supp.2d. 830 (S.D. Ind. 2009); *Hayes v. Howmedica Osteonics Corp.*, 2009 WL 6841859
2 (D.N.J. December 15, 2009); *Covert v. Stryker Corp.*, 2009 WL 2424559 (M.D.N.C. August 5,
3 2009); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243 (D.N.J. Mar. 5, 2009); *Parker v.*
4 *Stryker Corp.*, 584 F.Supp.2d 1298 (D. Colo. 2008); and *Notmeyer v. StrykerCorp.*, 2007 U.S.
5 Dist. LEXIS 69773 (N.D. Cal. Sept. 10, 2007). Many of these courts have dismissed the
6 actions on preemption grounds, and some have allowed claims to move forward past the
7 pleading stage. *Id.* While the Fifth and Seventh Circuit Courts of Appeals have weighed in on
8 these issues, the Ninth Circuit Court of Appeals has not. *See Bass, supra; Funk, supra; and*
9 *Bausch, supra.* However, the Court is well-instructed by the abundant case law examining the
10 issues present here.
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13 *Riegel* requires a two-step inquiry in determining whether a state claim is preempted by
14 the MDA pursuant to section 360k(a). *Riegel*, 552 U.S. 321-22. First, the Court must find that
15 the federal government has imposed requirements on the medical device at issue. *Id.* at 321. If
16 so, then the Court must determine whether Plaintiffs' claims are based on state requirements
17 that are "'different from, or in addition to' the federal ones, and that they relate to safety and
18 effectiveness." *Id.* at 321-22 (quoting 21 U.S.C. § 360k(a)). Because there is no question
19 either that the Trident™ System is a Class III medical device approved by the FDA through the
20 PMA process, or that Plaintiffs' claims relate to safety and effectiveness, preemption in this
21 case turns on whether the state claims are "parallel" – that is, whether they are premised on
22 violations of federal requirements applicable to this device, and neither differ from nor add to
23 such requirements.
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26 To properly allege parallel claims, a complaint must set forth facts showing "action or
27 inaction in [defendants'] efforts to take part in the PMA process or implement its results[.]"
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1 *Parker v. Stryker Corp.*, 584 F. Supp.2d 1298, 1301 (D. Colo. 2008) (quoting *Heisner ex rel.*
2 *Heisner v. Genzyme Corp.*, 2008 U.S. Dist. LEXIS 60569, 2008 WL 2940811 at *5 (N.D. Ill.
3 July 25, 2008)). The instant First Amended Complaint is very general in nature, relying almost
4 exclusively on the two warning letters sent by the FDA in 2007. While the First Amended
5 Complaint does allege that the Trident™ System was unreasonably dangerous and defective
6 because it “is believed to have originated in one of the two manufacturing facilities cited by the
7 letters from the FDA,” and that the device was “adulterated” as determined in those letters,
8 such conclusory allegations standing alone are not sufficient to sustain plaintiff’s burden of
9 pleading under *Twombly*. See Dkt. #10 at ¶¶ 4.4-4.7. “Without some factual allegation in the
10 complaint, it is hard to see how a claimant could satisfy the requirement of providing not only
11 ‘fair notice’ of the nature of the claim, but also ‘grounds’ on which the claim rests.” *Parker*,
12 584 F. Supp.2d at 1301 (citations omitted).

15 Plaintiffs’ references to the FDA warning letters do not sufficiently bolster the factual
16 basis for their claims. Setting aside potential problems of causation posed by attempting to link
17 letters issued in 2007 with Ms. Hernandez’s alleged injuries starting in 2005, Plaintiffs cannot
18 escape preemption solely by relying on the findings in the letters because they fail to provide
19 any factual allegations about how the alleged failure to develop or adhere to these practices and
20 procedures relate to the device Ms. Hernandez received in March of 2005 and her subsequent
21 injuries.
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24 In addition, Plaintiffs claims are not saved by their reliance on alleged violations of the
25 CGMPs. The Eastern District of New York recently examined a claim based on alleged
26 violations of the CGMPs and found the claim preempted. The Court wrote:

27 the law is clear that Plaintiffs must identify a specific federal regulation
28 allegedly violated. Here, Plaintiffs identify [sic] the CGMPs. Courts across

1 the country are generally split on this issue. Moreover, only the Sixth and
2 Seventh Circuits have directly spoken on this issue, both finding that
3 allegations founded on violations of CGMPs are sufficient to state a claim.
4 Despite this precedent, though, the Eastern District of New York has
5 generally held that parallel claims may not be predicated on violation of
6 CGMPs. Contrary to Plaintiffs' argument that there has been a shift toward
7 allowing such claims, Eastern District of New York precedent – including
8 Burkett, which was issued just a few months ago and after the parties
9 briefed the current motion – has held that the CGMPs do not identify a
10 federal law that is specific to the medical device at issue, thus forming an
11 insufficient basis for a parallel claim.

12 Moreover, Plaintiffs do allege that the Durata lead was adulterated in
13 violation of Section 501(h) of the FDCA and that the lead and/or
14 defibrillator had an impurity, imperfection, or other product defect. Even
15 assuming that such allegations assert a sufficient violation of federal
16 regulations, Plaintiffs have not sufficiently alleged how this violation
17 caused Plaintiffs' injuries. Specifically, the Amended Complaint alleges
18 that "Defendants violated federal law by making unsanctioned
19 adulterations" to the Durata lead. However, such assertions appear to be
20 based on the FDA warning letter, which simply stated that the Durata lead
21 was considered adulterated within the meaning of Section 501(h) because
22 "the methods used in, or the facilities or controls used for, their
23 manufacture, packing, storage, or installation" are not in conformity with
24 CGMPs. The specific CGMPs identified, though, do not have any direct
25 implications on how or why the Durata lead prematurely deteriorated.

26 Allegations regarding adulterations in particular can sufficiently state a
27 claim where the violation of CGMPs also indicate a deviation from PMA
28 requirements. In Purcel v. Advanced Bionics Corp., No. 07-CV-1777, 2008
U.S. Dist. LEXIS 62131, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008), for
example, the plaintiffs had sufficiently alleged a non-preempted claim
where they asserted that the defendant, subsequent to PMA, changed its
supplier, altered the device's mechanical configuration, and changed the
length, composition, and "firing" process for glass used in the device. The
result was that moisture levels within the cochlear implants exceeded the
maximums set out by the FDA, causing the device to malfunction.

29 Contrary to cases such as Purcel, Plaintiffs have failed to connect a
30 violation of the CGMPs with the violation of any federal regulation specific
31 to the devices at issue or explain how such violations caused Mr. Franzese's
32 injury. Formulaic recitation is insufficient. This is true, even though courts
33 have recognized that PMA documents are often confidential, making it
34 difficult for a plaintiff to plead the exact violation. Nonetheless, alleging
35 that a device was adulterated, without explaining how that adulteration
36 contravened federal law specific to the device fails to state a claim.

1 *Franzese v. St. Jude Med., Inc.*, 2014 U.S. Dist. LEXIS 85449, *11-15 (E.D.N.Y. June 23,
2 2014) (citations omitted). The Court finds this reasoning persuasive in the instant case, and
3 finds that, for the same reasons, Plaintiffs fails to state parallel claims.
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5 Finally, the Court examines Plaintiffs' warranty claim, as it is the only claim not clearly
6 preempted by *Riegel*. What makes this claim difficult to analyze is Plaintiffs' failure to specify
7 in the First Amended Complaint any way the alleged representations about the Trident™
8 System were communicated to them. Plaintiffs apparently plan to assert that "Defendant's [sic]
9 violated their warranties to Plaintiffs by manufacturing a device that was not in compliance
10 with federal regulations." Dkt. #16 at 20. Plaintiffs then discuss labeling requirements and the
11 requirement that devices conform to the representations contained on their labels. *Id.* at 20-22.
12 Accordingly, the Court interprets the claim at this time as one premised on the alleged failure to
13 conform with the product's labeling.
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16 Federal courts have been divided as to whether breach of express warranty claims are
17 preempted by section 360k. The Third and Seventh Circuits have held that such claims are not
18 preempted because any "requirements" imposed by the warranty are voluntarily assumed by the
19 warrantor, not imposed by the state. *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th
20 Cir. 1997), *cert. denied*, 523 U.S. 1020, 118 S. Ct. 1300, 140 L. Ed. 2d 467 (1998); *Michael v.*
21 *Shiley, Inc.*, 46 F.3d 1316, 1327-28 (3rd Cir.), *cert. denied*, 516 U.S. 815, 116 S. Ct. 67, 133 L.
22 Ed. 2d 29 (1995), *overruled on other grounds as stated in In re Orthopedic Bone Screw*
23 *Products Liability Litigation*, 159 F.3d 817, 825 (3rd Cir. 1998). *See also In re Medtronic, Inc.*
24 *Implantable Defibrillators Litigation*, 465 F.Supp.2d 886, 898 (D. Min. 2006); *Davenport v.*
25 *Medtronic, Inc.*, 302 F.Supp.2d 419, 433 (E.D. Pa. 2004); *Steele v. Depuy Orthopaedics, Inc.*,
26 295 F.Supp.2d 439, 455-56 (D.N.J. 2003). Other courts have found this reasoning
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unpersuasive because all representations regarding the device in its labeling must be approved by the FDA as part of the PMA process. Therefore, these courts have held any claim that such representations are inadequate is preempted. *See Enlow v. St. Jude Medical, Inc.*, 210 F.Supp.2d 853, 861-62 (W.D. Ky. 2001) (citing *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1100 (6th Cir. 1997), *cert. denied*, 522 U.S. 1075, 118 S. Ct. 850, 139 L. Ed. 2d 751 (1998)).

In *Parker v. Stryker Corp.*, *supra*, the Court examined preemption in light of the *Riegel* decision, ultimately finding the warranty claim to be preempted. The Court explained that “[t]he premarket approval process includes review of the device’s proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label and must determine that the proposed labeling is neither false nor misleading.” *Parker*, 584 F. Supp.2d at 1303 (citing *Riegel*). “Moreover, once approved, the device’s labeling may not be altered without first obtaining FDA approval ‘under largely the same criteria as an initial application.’” *Id.* As a result, the *Parker* Court determined that the express warranty claim would contradict the FDA’s determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements, and therefore such claims are preempted by section 360k. *Id.*

The Court also finds such reasoning persuasive in this case, particularly given the lack of specificity in the First Amended Complaint. Accordingly, all of Plaintiffs’ claims are preempted and it is not necessary to reach Defendants’ alternative arguments.

E. Leave to Amend

Ordinarily, leave to amend a complaint should be freely given following an order of dismissal, “unless it is absolutely clear that the deficiencies of the complaint could not be cured

1 by amendment.” *Noll v. Carlson*, 809 F.2d 1446, 1448 (9th Cir. 1987); *see also DeSoto v.*
2 *Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992) (“A district court does not err in
3 denying leave to amend where the amendment would be futile.” (citing *Reddy v. Litton Indus.,*
4 *Inc.*, 912 F.2d 291, 296 (9th Cir. 1990)). Accordingly, if Plaintiffs wish to amend their First
5 Amended Complaint, they are permitted to file a motion for leave to amend within 20 days of
6 the date of this Order. The motion should attach any proposed Second Amended Complaint.
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8 The motion should also cite relevant authority explaining why leave to amend is appropriate,
9 and why the proposed amendments will not fall victim to the legal authorities discussed above.

10 IV. CONCLUSION

11 Having reviewed the relevant pleadings, the declarations and exhibits attached thereto,
12 and the remainder of the record, the Court hereby ORDERS:
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- 14 1) Defendants’ Motion to Dismiss (Dkt. #14) is GRANTED.
- 15 2) If Plaintiffs wish to amend their First Amended Complaint, they are permitted to file
16 a motion for leave to amend as noted above.

17 DATED this 11th day of December 2014.
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20 RICARDO S. MARTINEZ
21 UNITED STATES DISTRICT JUDGE
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